osmotically effective solute) (page 8, 2nd-3rd paragraph; page 9, 1st-2nd paragraph; and page 10, last paragraph through page 11, 2nd-3rd paragraph). The core is then coated with a film coating (page 9, paragraph 3 through page 10; page 11, paragraphs 2-3). Drug includes antibiotics, antihypertensives, antiparkinson, hypnotic, and those disclosed in page 5, 4th paragraph. The composition can be prepared in granule (multiparticulate) form, the granule can then be compressed into tablet, and the tablet is coated with a film (page 11; and examples).

It is noted that Kerc does not explicitly teach at lease one delivery port. However, it is the position of the examiner that the exit port is an inherent feature, because Kerc teaches the use of the same drug (amorphous agent), the same osmotic agent (hydroxyethyl cellulose, hydroxypropyl cellulose, or hydroxypropylmethyl cellulose), the same osmotically effective solute (mannitol, sorbitol, glucose, or sodium chloride), the same dispersing polymer (hydroxypropylmethyl cellulose), and the same water-permeable coating. Accordingly, the water-permeable coating of the same polymer would have the same properties, e.g., porous (deliver ports). Applicant's specification at page 23, lines 16-29, and page 24, lines 13-22, defines delivery ports as any opening or pores that are formed *in situ* during use. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, when the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The rejection is traversed on the basis that Kerc does not disclose all elements of Applicants' invention, hence cannot anticipate. Kerc does not anticipate because Kerc does not disclose (1) a coating that is "non-dissolving and non-eroding during release of said drug" (2) a delivery port and (3) a coating that controls the "influx of water to said core from an aqueous environment of use to cause extrusion of at least a portion of said core through said at least one delivery port".

Kerc does not disclose a non-dissolving, non-eroding coating. Kerc discloses a coated matrix delivery system comprising a core of drug-containing granules that also comprise a controlled release matrix, the core having a coating surrounding it as a "third phase". Both polymers listed as suitable for use in the Kerc's coating (see Kerc at page 9) are enteric, meaning that they dissolve once the dosage form has passed the upper GI tract and reached the higher pH region of the intestines. Kerc himself describes the coating as being "...poorly soluble or gastro-resistant ...for additional delay in release" illustrating the coating's clear function in delaying release until the dosage form is past the upper GI tract. Kerc's disclosure is thus related to an altogether different controlled release dosage form than an osmotic dosage form.

Because Kerc does not relate to osmotic dosage forms, Kerc does not disclose a delivery port of any type, as required elements in Applicants' claims. Indeed, it would make no sense for Kerc to disclose a port since that would defeat the purpose of his invention, this being discussed further below.

The Examiner's argument that a port is inherent is noted, but traversed. Ports are implemented in osmotic dosage forms by physical means, for example by physically laser drilling through a tablet coating, or by forming the pore during the coating process, or by forming the port *in situ* during use. See Applicants' specification at pages 23-24 where pore formation is discussed extensively. Under inherency law a result, in this case port formation, must be inevitable. Thus a rejection grounded in inherency requires that a port would inevitably or necessarily be formed in the Kerc dosage forms. The law on this is well established and is discussed further below.

Inherency will not lie because Kerc never discloses forming a port or any means for forming one. Kerc never mentions the word "port", never discloses forming an orifice in his coating, and never mentions any reason for doing so. Implementing a port in Kerc would negate his invention. As noted above, both polymers listed as suitable for use in Kerc's coating (see Kerc at page 9) are enteric, meaning that they dissolve once the dosage form has passed the upper GI tract and reached the lower (higher pH) GI tract. Kerc's description of his polymer film coating as being "...poorly soluble or gastro-reistant ...for additional delay in release" illustrates his purpose of delaying release. Implementing a delivery port in Kerc as required by Applicants would immediately (i.e., upon swallowing) defeat that purpose by exposing Kerc's core to the GI environment.

The inherency standard is otherwise an exacting one, one that Kerc does not meet:

> Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element is "necessarily present in the thing described in the references, and that it would be so recognized by persons of ordinary skill."

Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1380 (Fed. Cir. 2002) (citations omitted).

Furthermore,

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). In respect of the instant §102 rejection, the Examiner has provided no basis that a port would ever be formed in Kerc, let alone necessarily be formed, as inherency requires. And, for the reasons discussed above, it makes no sense that Kerc would want to form a port in his device since a port would defeat its operation.

In addition to the fact that ports are in no way inherent (and are in fact undesirable) in Kerc, Applicants note the requirement that the coating control the influx of water so that at least a portion of the core is extruded through the delivery port. This requires formation of a port in a coating that is non-dissolving and non-eroding during

release of the drug. A coating that is "non-dissolving and non-eroding during release" is an additional element not disclosed in Kerc, whose invention would be inoperable if his coating were non-dissolving and non-eroding. Kerc provides a coating that delays release, not one that prevents it altogether. The coating of Kerc dissolves as pH increases along the GI tract in order for the dosage form to release drug. Kerc's coating does not remain intact with a defined delivery port so as to control the influx of water so as to extrude a portion of the core through the delivery port. In fact, applicants' non-eroding and non-dissolving coating would prevent Kerc from releasing any drug at all.

In fact, Kerc expressly states that his dosage form does not operate in the manner of an osmotic dosage form, the type claimed by applicants. See page 4, bottom of second paragraph of WO96/36318.

Another contention raised by the Examiner pursuant to making the anticipation rejection over Kerc was that chemical compositions must be the same if they contain the same chemical structure. Office Action, paragraph bridging pages 5 and 6:

> Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable, Therefore, when the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 f.2d 705,709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The Examiner's comments are traversed. As discussed above, the chemical composition of claim 1 is different than that disclosed in Kerc because Kerc does not in fact use "the same water-permeable coating". Moveover, the examiner's reasoning is faulty because it is indeed possible for compositions to contain the same components and yet be different differ due to the fact that they differ structurally. The Spada case is inapposite as it did not deal with dosage forms that are physically structurally different. Spada dealt with a claimed polymer and a prior art polymer that appeared to be derived from the same monomers. Applicants note it is very possible for two compositions, i.e., dosage devices, to contain the same components but to differ structurally and thereby function in different manners. To give an analogy, chocolate cakes and chocolate chip cookies contain many of the same ingredients, but they have different structures such that nobody would contend that they are the same. Extending the analogy to the instant facts, enteric polymers are known for use as coatings that resist degradation in the low pH (acid) environment of the upper GI tract but that readily dissolve in the higher pH environment of the lower GI tract. That is the fashion in which they are employed in Kerc. But Kerc's enteric coating is unrelated to Applicants' who employ cellulosic polymers (some of which are enteric) to make dispersions of drug and cellulosic polymers that are located within the core of the dosage form. Used in this fashion, the cellulosic polymers function to increase the concentration of dissolved drug as the

dispersions are extruded from the core regardless of the dosage form's position along the GI tract. Thus, the dispersions made by Applicants using cellulosic polymers are wholly different in structure, purpose and effect from the enteric coatings disclosed by Kerc.

It is well accepted that the standard for anticipation is one of strict identity, meaning that for prior art to anticipate, it must contain all of the essential elements. Hybritech Inc. v. Monoclonal Antibodies, Inc.231 USPQ 81 (Fed Cir 1986). See In re Donohue, 226 USPQ 619 (Fed Cir 1985) where it was stated:

> an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device.

Clearly, Kerc does not require all of the elements in Applicants' claims, whether or not inherency is invoked. Essentially the whole of Applicants' subparagraph (b) of independent claim 49 is missing from and not suggested in Kerc. More specifically, Kerc does not disclose the following elements required by Applicants:

1. An osmotic dosage form

2. A port for drug release (which would in fact defeat Kerc's purpose of delaying release).

3. A coating that is non-eroding and non-dissolving. Kerc's coating, being enteric, dissolves and releases in the lower GI tract.

Accordingly, withdrawal of the anticipation rejection over Kerc is accordingly respectfully requested.

Claims 58, 59, and 73-75 were rejected under 35 USC 103(a) over Faour, US 6,004,582 in view of Kerc. The Examiner relied upon Kerc for the reasons previously stated in the Office Action. The Examiner appeared to be relying on Faour because it discloses an osmotic device. The Examiner commented in pertinent part as follows:

> Faour teaches an osmotic device comprising a core comprises an active agent, an osmotic agent and polyvinyl pyrrolidone; a semi-permeable membrane; and a passage way (column 4, lines 63 through column 5, lines 1-30; and column 9, lines 52-58). Active agent is disclosed in columns 14-15. Semi-permeable membrane is made of material that remains its chemical and physical integrity in the environment of use (column 9, lines 1-16). The core further includes osmotically effective solutes (column 9, lines 38-51). Faour further teaches the use of tablet binder such as polyvinyl pyrrolidone, cellulose material, polypropylene glycol, and polyoxyethylene-polyoxyproprylene copolymer (column 10, lines 35-57).
>
> Faour does not explicitly teach solid dispersion of a drug in its amorphous form. However, Kerc teaches dispersing an amorphous active agent in polymers is especially suitable for active agents which exhibit poor solubility in crystal form (abstract). Thus, it would have been obvious to one of ordinary skill in the art to prepare the osmotic device of Faour using the solid dispersion of an amorphous drug in view of the teaching of Kerc, because Kerc teaches using amorphous active agent in which the solubility and the dissolution rate of the active agent will be independent of its polymorphous form, crystallinity, particle size and specific

surface area, because Kerc teaches crystalline active agents have the essential disadvantage due to the presence of the crystalline in several polymorphous modification, crystal size, and results in a release rate that is not constant, because Faour teaches the use of poorly soluble drugs, and because Faour teaches the osmotic device can be prepared according to methods known in the art.

The rejection is traversed on the basis that the references, Faour and Kerc are not properly combinable. Kerc, as noted above, relates to a matrix controlled release dosage form. The Examiner has provided no basis as to how or why, absent Applicants' specification, the Kerc reference relating to a matrix controlled release device should be combined with the Faour reference relating to an osmotic dosage form, a dosage delivery device that differs from Kerc in structure and mechanism of delivery. Other than the fact that both references disclose a dosage delivery device, they are not combinable because osmotic devices like the one in Faour are unrelated to matrix controlled release devices like the one in Kerc. Osmotic devices release through a port whereas the delivery device in Kerc releases directly from a matrix after the surrounding membrane dissolves away at the relatively higher pH encountered in the lower GI tract. The operation and mechanisms of release are completely different. For that reason one of ordinary skill in the art would not find it obvious to combine the references, particularly as the Examiner has done, i.e., by inserting a piece from one reference into the other, but with no suggestion to do so in the art itself.

The Federal Circuit Court has held that it is error for the USPTO to reject a claimed invention as an obvious combination of the teachings of two prior art references when the prior art provided no teaching, suggestion or incentive supporting the combination. "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination." *In re Bond*, 910 F2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990); *See also ACS Hospital Systems, Inc. v. Montefiori Hospital*, 732 F.2d 1572, 1577 (Fed. Cir. 1984).

The Federal Circuit Court has further held that, in questions of obviousness, one "cannot pick and choose among the individual elements of assorted prior art references to recreate a claimed invention." *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 887, 8 USPQ2d 1468, 1475 (Fed. Cir. 1988).

The Federal Circuit previously stated that the mere fact that references can be combined does not cause the resulting combination to be obvious absent the prior art suggesting the combination. ACS Hospital Systems, Inc. v. Montefoire Hospital, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). In making such a combination, "there must be some reason for the combination other than the hindsight gleaned from the invention itself." Interconnect Planning Corp. v. Feil, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). It is not

permissible to treat the claims at issue as a frame and the cited prior art references as a mosaic to create a facsimile of the claimed invention. W.L. Gore Associates, Inc. v. Garlock, Inc., 220 U.S.P.Q. 303, 312 (Fed. Cir. 1983).

Applicants accordingly submit that the Examiner has failed to present any teaching, suggestion or incentive supporting the combination of the disparate references cited, it being impermissible, as discussed above, to assemble a likeness of Applicants' invention from the unrelated bits and pieces cited by the Examiner from Kerc and Faour.

Claims 49-78 were rejected under 35 USC 103(a) as being unpatentable over Faour et al., in view of Kigoshi et al. US 6,254,889. Faour was relied upon for the reasons disclosed in the Faour v. Kerc rejection. The Examiner noted that Faour does not explicitly teach solid dispersions of a drug in its amorphous form, as well as the use of a specific dispersion polymer such as hydroxypropylmethyl cellulose acetate succinate.

The Examiner further stated, in pertinent part, that

> Kigoshi teaches a solid dispersion dosage form of a slightly soluble drug comprising dispersing an amorphous drug in a dispersion polymer including hydroxypropylmethyl cellulose acetate succinate (see abstract; and column 3, lines 18-33). The dispersing solution is sprayed onto an absorbent carrier to obtain a drug core. The core is than mixed with excipient, and made into dosage form (column 4, lines 39-67). Thus, it would have been obvious to one of ordinary skill in the art to prepare the drug core of Faour using the solid dispersion of an amorphous drug in view of the teaching of Kigoshi, because Kigoshi teaches slightly soluble drugs have high crystallinity and low bioavailability, because Kigoshi teaches improving the solubility and bioavailability of slightly soluble drugs by dispersing slightly soluble drug in a polymer to form a solid dispersion, because Faour teaches the use of poorly soluble drugs, and because Faour teaches the osmotic device can be prepared according to methods known in the art.

The above discussion relating to Faour v. Kerc is equally applicable to Faour v. Kigoshi. Kigoshi discloses dispersions of xanthines. Faour relates to an osmotic device. As between Faour and Kigoshi, there is no suggestion to use a dispersion like any of those disclosed in Kigoshi in an osmotic delivery device. Only Applicants have made such a suggestion in the instant application, it being noted that Applicants' specification may not be used as prior art against them. Kigoshi simply discloses that some of the polymers useful as dispersion polymers in Applicants' invention are known. Faour simply discloses an osmotic dosage form with no disclosure of improving the solubility of the drug therein. Kigoshi does not remedy the shortcomings of Faour because there is no suggestion in Kigoshi that would lead one of ordinary skill to modify the teachings in Faour, or vice-versa.

The only way that one of only ordinary skill in the art would combine Faour and Kigoshi in the same manner as the Examiner is through the impermissible use of hindsight. Given the art cited, Applicants' invention is not even "obvious to try", realizing

that the law is emphatic that "obvious to try" is NOT the test of obviousness under 35 U.S.C. §103. American Hospital supply Corp. v. Travenol Laboratories, Inc., 223 USPQ 577, 582 (Fed. Cir. 1984). The Federal Circuit has explained the proper test:

> The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out **and would have a reasonable likelihood of success**, viewed in light of the prior art. **Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure** (emphasis added).

In re Dow Chemical Co., 5 USPQ.2d 1529, 1531 (Fed. Cir. 1988); Amgen, Inc. V. Chugai Pharmaceutical Co. Ltd. 18 USPQ.2d 1016. 1022-23 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991). Neither a suggestion of the dosage form itself nor any likelihood of success (i.e., of providing any benefit) would be expected based on Faour and Kigoshi, however.

It is accordingly respectfully submitted that the rejection of claims 49-78 over Faour in view of Kigoshi should be withdrawn.

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

Date: September 5, 2006

James T. Jones
Attorney for Applicant(s)
Reg. No. 30,561

Pfizer Inc.
Patent Department, Box 8260-1611
Eastern Point Road
Groton, CT 06340
(860) 441-4903